

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ulrike SCHULZ et al.

Confirmation No.: 2144

Group Art Unit: 1613

Serial No. : 10/574,231

Examiner: Lea, Christopher Raymond

I. A. Filed : March 10, 2005

For : TRANSPARENT COSMETIC OR DERMATOLOGICAL FORMULATION

REPLY BRIEF UNDER 37 C.F.R. § 41.41(a)(1)

Commissioner for Patents

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Sir:

This Reply Brief is in response to the Examiner's Answer mailed October 27, 2011, the period for reply extending until December 27, 2011.

In the Examiner's Answer all grounds of rejection set forth in the final rejection with the exception of the provisional rejection of claims 34-36 and 38-45 on the ground of nonstatutory obviousness-type double patenting based on application No. 10/574,230 are maintained.

Appellants note that the Examiner's Answer does not sufficiently address several of Appellants' arguments as to why the rejections are without merit, and misrepresents some of the facts. These deficiencies have prompted the present Reply Brief.

Appellants also note that this Reply Brief is being filed under 37 C.F.R. § 41.41(a)(1) and is directed to the arguments presented in the Examiner's Answer, and therefore must be entered unless the final rejection is withdrawn in response to the instant Reply Brief.

In order to avoid repetition, the following response to the Examiner's arguments in the Examiner's Answer is limited to issues which are important enough to warrant a further

comment in Appellants' opinion. Accordingly, Appellants' silence with respect to any allegations set forth in the Examiner's Answer that are not specifically addressed below should by no means be construed as Appellants' admission that these allegations are of any merit.

REPLY

1. Appellants note that the Examiner maintains the position that claims 49, 50 and 53 are anticipated by Williams et al., GB 2280111 (hereafter "WILLIAMS"). Appellants still disagree with the Examiner in this regard for at least the reasons set forth in the Appeal Brief.

It is pointed out again that independent claim 49 recites, *inter alia*, that in the claimed cosmetic or dermatological antiperspirant formulation (a) an antiperspirant active ingredient which comprises one or more aluminum salts, (b) at least one α -hydroxycarboxylic acid and (c) water are present in ratios which result in gelling and there is no support whatsoever for the Examiner's allegation that in the composition of Example 9 of WILLIAMS aluminum chlorohydrate (allegedly a combination of aluminum chlorohydrate and propylene glycol), lactic acid and water are necessarily present in ratios which result in gelling. On the contrary, the fact that the composition of Example 9 of WILLIAMS contains 3 % by weight of dibenzylidene sorbitol, i.e., a substance which is expressly mentioned in WILLIAMS as the preferred gelling agent for use in the clear gel antiperspirant compositions of WILLIAMS allows no reasonable conclusion other than that in this composition aluminum chlorohydrate, lactic acid and water are not present in ratios which result in gelling. Otherwise the presence of

considerable amounts of a (separate) gelling agent in this composition would not make any sense at all.

Appellants note that in this regard the Examiner now essentially argues (for the first time) that the rejected claims recite the term “gelling” and that in light of page 3, lines 12-14 of the instant specification this term does not mean the same as “forming a gel” but merely requires that components (a), (b) and (c) are present in ratios which thicken the composition. In this regard, the Examiner further asserts that “gel” when used as a verb means no more than “to thicken” (without providing any evidence whatsoever to support this assertion). See paragraph bridging pages 12 and 13 of the Examiner’s Answer.

In response, it is pointed out that the present specification makes it abundantly clear that the claimed compositions are not merely “thickened” compositions but compositions which are present as a gel. See, for example, page 5, lines 20-22 (“The preparation according to the invention is easy to apply in gel form and has a pleasant feel on the skin on account of the lack of stickiness.”) and page 9, lines 11-14 of the instant specification (“The transparent gel-like preparation according to the invention is advantageously prepared by dissolving the α -hydroxycarboxylic acids in water. The aqueous AP active ingredients, in particular aluminum salt solution, are then added with stirring.”)

At any rate, WILLIAMS even provides evidence that one of ordinary skill in the art would not consider gelling agents and thickening agents to be the same. For example, at page 8, lines 1-5 of WILLIAMS preferred concentrations of the gelling agent which must be present in the compositions disclosed therein are set forth. In the subsequent

paragraph (page 8, lines 6-11) WILLIAMS states that “[o]ther optional components such as thickening agents, liquid emollients, emulsifiers, dyes and fragrances can also be included in the composition ...”. Emphasis added. Also the composition of Example 9 of WILLIAMS relied upon by the Examiner is not identified as a thickened composition but as a “clear gel stick”.

2. Appellants also challenge the Examiner’s implicit assertion that the fact that the concentration of water and the ratio of water with respect to components (a) and (b) that are necessary for gelling the composition of the present invention are not mentioned at page 8, lines 5-7 of the instant specification “leads one of ordinary skill in the art to conclude that nearly any amount of water combined with the α -hydroxycarboxylic acid and antiperspirant active ingredient would ‘result in gelling’”. Page 13, second paragraph of the Examiner’s Answer. It is submitted that one of ordinary skill in the art will readily appreciate that the concentration of water and the ratio of water with respect to components (a) and (b) that are necessary for gelling a specific composition depends to a large extent on the specific substances which are employed as α -hydroxycarboxylic acid and as antiperspirant active ingredient respectively (and the relative ratio thereof), wherefore it would not make sense to indicate any concentration or relative ratio of water that is necessary for gelling a composition in the absence of any information as to which specific α -hydroxycarboxylic acid and which specific antiperspirant active ingredient are to be employed.

3. Regarding the assertions in the paragraph bridging pages 14 and 15 of the Examiner's Answer Appellants submit that the Examiner appears to have misunderstood the remarks in the paragraph bridging pages 13 and 14 of the Appeal Brief. Appellants merely intended to make it clear that the only potential support that the Examiner could have had for asserting that in the composition of Example 9 of WILLIAMS aluminum chlorohydrate, lactic acid and water are present in ratios which by themselves (i.e., even without the presence of a separate gelling agent) would have resulted in gelling would have been if in one of the compositions which are exemplified in the instant specification the same or similar substances (a), (b) and (c) would have been present in the same or similar relative ratios as in the composition of Example 9 of WILLIAMS. However, this is not the case. Merely by way of example, the amount of water in the composition of Example 9 of WILLIAMS is about 5 % by weight (resulting in a ratio of component (c) with respect to components (a) and (b) which is relatively small) whereas all of the compositions which are exemplified in the instant specification comprise at least 87 % by weight of water (resulting in a ratio of component (c) with respect to components (a) and (b) which is quite large). Accordingly, a comparison of the composition of Example 9 of WILLIAMS and the compositions exemplified in the instant specification clearly does not allow any conclusion as to whether in the composition of Example 9 of WILLIAMS aluminum chlorohydrate, lactic acid and water are present in ratios which would have resulted in a gelling of the composition even without the simultaneous presence of the separate gelling agent (3 % by weight of dibenzylidene sorbitol).

That water and lactic acid are not even intended to participate in the formation of a gel in a composition according to WILLIAMS also becomes clear from the fact that

lactic acid is intended to function as a buffering agent (see, e.g., page 5, line 25 to page 6, line 8 of WILLIAMS) and that water is an (equally) optional component of the compositions of WILLIAMS. In particular, the intended function of water merely is to “prevent syneresis or sweating of the composition on exposure to air” and water “can also be used to give the composition a dry feel as opposed to a sticky feel”. Further, “[w]hen water is present in the composition, there must be sufficient gelling agent to cause the composition to solidify at a temperature of less than or equal to about 90°C...” (see, e.g., col. 5, lines 25-35 of WILLIAMS). Emphasis added. This is a clear indication that in the composition of WILLIAMS, water does not play any part in the gelling process.

4. Regarding the rejection of claims 34-57 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Guskey et al., U.S. Patent No. 5,776,494 (hereafter “GUSKEY”) in view of Bhakoo et al., US 2003/0059396 A1 (hereafter “BHAKOO”) and Hei et al., U.S. Patent No. 6,593,283 (hereafter “HEI”), Appellants point out again that

(a) GUSKEY clearly discourages the presence of significant amounts of water in the compositions disclosed therein (“the pharmaceutical gel compositions of the present invention preferably contain less than about 5%, preferably less than about 3%, more preferably less than about 1%, most preferably zero percent, by weight of free or added water, other than the water of hydration typically associated with the pharmaceutically acceptable actives prior to formulation”), let alone provides an apparent reason for one of ordinary skill in the art to employ water and in particular, water in an amount which results in gelling in the (hypothetical) case that an antiperspirant and an exfoliating agent such as mandelic acid are simultaneously present in the composition as well,

(b) the compositions of GUSKEY already contain a separate and specified gelling agent, i.e., an agent whose very purpose it is to cause (result in) the formation of a gel, which is yet another reason why GUSKEY fails to prompt one of ordinary skill in the art to adjust the ratio of antiperspirant active ingredient, exfoliating agent such as α -hydroxycarboxylic acid and water (assuming, *arguendo*, all of these components can reasonably be expected to be present at the same time in a composition according to GUSKEY) to result in gelling, i.e., to independently form a gel by themselves, in addition to the gel that is already formed by the gelling agent (if possible at all).

In this regard, Appellants submit that the question here is not whether or not GUSKEY teaches away from employing water in the compositions disclosed therein but rather is whether despite the unmistakable recommendation in GUSKEY to avoid the presence of even small amounts of water if possible, GUSKEY provides an apparent reason for one of ordinary skill in the art to not only employ water but to additionally and deliberately adjust the ratio of water, antiperspirant and exfoliating agent (which is a merely hypothetical combination) in a way that gelling of the composition will result even in the absence of the required separate gelling agent of the formula shown in, e.g., claim 1 of GUSKEY. Clearly, GUSKEY cannot be considered to teach that water is a result-effective variable whose concentration should be optimized (other than teaching that the “optimum” concentration of water is zero).

At any rate, even if one were to assume, *arguendo*, that GUSKEY discloses concentrations of water in the compositions disclosed therein which in combination with properly selected concentrations of antiperspirant and exfoliating agent disclosed therein could be considered to theoretically result in gelling of the composition, the Examiner is

reminded that “it is not enough to simply show that the references disclose the claim limitations; in addition, ‘it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.’” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617, F.3d 1296, 1303 (Fed. Cir. 2010). Further, it is also necessary for the Examiner to properly construe what an applied reference *fairly* teaches or discloses. See, e.g., *In re Fracalossi and Wajer*, 681 F.2d 792 (CCPA 1982).

5. BHAKOO and HEI are unable to cure any of the deficiencies of GUSKEY for the at least the reasons set forth in the Appeal Brief. Regarding the Examiner’s allegation at page 17, first paragraph of the Examiner’s Answer that BHAKOO and HEI teach that mandelic acid has antimicrobial properties it is pointed out again that BHAKOO does not even appear to mention mandelic acid and that according to HEI mandelic acid is only one representative of a laundry list of compounds which may optionally be employed in addition to the primary antimicrobial compounds, i.e., the antimicrobially active solvents as set forth in col. 7, lines 1-45 thereof.

6. At page 17, second paragraph of the Examiner’s Answer it is alleged that Appellants’ statement that the Examiner has not addressed the fact that the instant claims recite a transparent cosmetic or dermatological formulation is “clearly false” and that the Examiner has pointed out that GUSKEY “teaches that the compositions have reduced visual residue (column 2, lines 19-24).”

In this regard, it is pointed out that the mere fact that a composition provides a reduced visual residue (after application to skin) apparently does not allow any conclusion with respect to the optical properties of the composition and in particular, the transparency of the composition as such, i.e., before its application to skin. Clearly, even a non-transparent composition can be capable of providing a “reduced visual residue” (whatever the basis for this comparison is supposed to be) after application to skin. Conversely, a transparent composition may leave behind a clearly visible residue after application to skin (e.g., after evaporation of the transparency-imparting components such as solvents). In other words, GUSKEY neither teaches nor suggests that the compositions disclosed therein are, or are intended to be transparent.

It further is not seen that the compositions of GUSKEY and the claimed compositions “have the same chemical composition”, as also alleged by the Examiner.

7. Regarding the absence of unexpected results alleged in the paragraph bridging pages 18 and 19 of the Examiner’s Answer the Examiner is reminded that “[i]n rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d, 1531, 1532 (Fed. Cir. 1993), citing *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). For at least the foregoing reasons it is not seen that the Examiner has met the burden of presenting a *prima facie* case of obviousness, wherefore Appellants are under no obligation to present unexpected results.

CONCLUSION

For at least the foregoing reasons and the additional reasons set forth in the Appeal Brief, the request to reverse the rejections of claims 34-57 and to return the instant application to the Examining Group for prompt allowance is respectfully maintained.

Although no fee is believed to be required for entry of this Reply Brief, the Patent and Trademark Office is hereby authorized to charge any fee that is deemed to be necessary to Deposit Account No. 19-0089.

Respectfully submitted,
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